In re: Waldon et al. Serial No.: 10/029,423

Filed: December 20, 2001

Page 2 of 5

In the Specification:

Please replace publication paragraph [0008] with the following amended paragraph:

[0008] Another aspect of female sexual dysfunction is aberrations in the clitoral erectile response. Such response is an interplay of the autonomic nervous system, endocrine system and the circulatory system. Although the failure of erectile response (impotence) is most commonly associated with men, it is also an aspect of female sexual dysfunction. Increased blood flow is necessary for a clitoral erection along with vaginal engorgement. Regular stimulation of clitoral and vaginal blood flow is necessary for healthy and functional vaginal and clitoral tissue. Also there is evidence that blood flow is related to the achievement of orgasm in women, although the relationship is not as clear as it is for men. It has been suggested that the addition of vasodilators can be used to improve female sexual response. For example, U.S. Patent Nos. 5,565,466 to Gioco et al., 6,051,594 to Lowrey and 6,011,043 to Estok suggest the use of phentolamine. U.S. Patent Nos. 5,891,915 to Wysor et al. and 6,046,240 to See propose the administering administration of prostaglandin E. Additionally, other patents issued to Place et al. including U.S. Patent No. 6,294,550 and U.S. Patent No. 6,306,841 provide methods of treating a sexual dysfunction in a female individual by administering a vasoactive agent to the vagina, vulval area or urethra of the individual undergoing treatment.

Please replace publication paragraph [0015] with the following amended paragraph:

[0015] In one aspect, the invention relates to a pharmaceutical composition. The pharmaceutical composition comprises a therapeutically effective amount of an estrogenic compound, androgenic compound, vasodilation compound, and a pharmaceutically acceptable carrier. Alternatively, in another aspect of the invention, the pharmaceutical composition may comprise a therapeutically effective amount of an androgenic compound, a therapeutically effective amount of a vasodilation compound,

In re: Waldon et al. Serial No.: 10/029,423 Filed: December 20, 2001

Page 3 of 5

and a pharmaceutically acceptable carrier. A "therapeutically effective" amount as used herein is an amount of an estrogenic compound, androgenic compound and vasodilation compound that is sufficient to treat (e.g. increase, boost, augment) sexual function in a subject. The therapeutically effective amount will vary with the age and physical condition of the patient, the severity of the treatment condition being treated, the duration of the treatment, the nature of any concurrent treatment, the pharmaceutically acceptable carrier used and like factors within the knowledge and expertise of those skilled in the art. Pharmaceutically acceptable carriers are preferably liquid, particularly aqueous, carriers, the selection of which are known in the art.

Please replace publication paragraph [0018] with the following amended paragraph:

[0018] Suitable androgenic compounds include methyltestosterone, androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androsteronediol, androsteronediol-3-acetate, androsteronediol-17-acetate. androsteronediol 3-17-diacetate, androsteronediol-17-benzoate, androsteronedione, androstenedione. androstenediol, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, androsteronediol-3-acetate-17-benzoate, oxandrolone, oxymetholone, stanozolol, testosterone, testosterone decanoate, 4dihydrotestosterone, 5α-dihydrotestosterone, testolactone, 17α-methyl-19nortestosterone and pharmaceutically acceptable esters and salts thereof, and combinations of any of the foregoing. Preferably the therapeutically effective amount of the androgenic compound is equivalent to oral doses of about 0.15 to about 5 mg of methyl testosterone. Vasodilation compounds or agents facilitate the clitoral erectile response in females as a result of engorgement of the erectile tissues of the genitalia with blood in response to sexual stimulation. Suitable vasodilation compounds include alpha adrenergic antagonists. Exemplary a-adrenergic compounds include phentolamine, phenoxybenzalamine, tolazoline, doxazosin, dibenamine, prazosin,

In re: Waldon et al. Serial No.: 10/029,423 Filed: December 20, 2001

Page 4 of 5

prazosin hydrochloride, phenoxybenzamine and the like. Preferably, phentolamine is used and can form pharmaceutically acceptable salts with organic and inorganic acids, such as described in U.S. Patent No. 6,001,845 to Estok, the disclosure of which is incorporated herein by reference in its entirety. Preferably phentolamine mesylate or phentolamine hydrochloride is used. Optionally apomorphine or other opiate derivatives may be used with phentolamine. Other vasodilation compounds include phosphodiesterase type 5 inhibitors (e.g., suldenafi sildenafil), prostaglandin E compounds (e.g., alprostodil), thymoxamine, bromocriptine, yohimbine, paperverine, organic nitrates, imipramine, verapamil, naftidrofuryl, and isoxsuprine. Combinations of the various vasodilation compounds may be used. Preferably, the therapeutically effective amount for oral use of vasodilation compound is equivalent to doses of about 5 to about 80 mg, and preferably about 20 about 80 mg of phentalomine hydrochloride or mesylate.

Please replace publication paragraph [0034] with the following amended paragraph:

[0034] The present invention is explained in greater detail in the Examples which follow. These examples are intended as illustrative of the invention and are not to be taken are as limiting thereof.